



December 23, 1999

Kathleen Reedy  
Food and Drug Administration  
Center for Drugs Evaluation and Research  
Office of Review Management  
Advisors and Consultants Staff  
HFD-21, Room 1093  
5630 Fishers Lane  
Rockville, MD 20852-1734

**Re: NDA 21-120, NOVANTRONE® (mitoxantrone hydrochloride)  
For the Treatment of Progressive Multiple Sclerosis  
Briefing Document for Peripheral & CNS Drugs Advisory Committee  
AVAILABLE FOR PUBLIC DISCLOSURE WITHOUT REDACTION**

Dear Ms. Reedy:

Per our discussion this morning, enclosed please find 2 copies of Immunex Corporation's briefing document for Novantrone for the treatment of progressive multiple sclerosis. The copies provided do not contain either the "CONFIDENTIAL" statement on the inside front cover nor do they contain that term in the header on each page. The product will be reviewed at the January 28, 2000 meeting of the Peripheral and CNS Drugs Advisory Committee. Per your request I am also providing a copy of the attached document as a PDF file on a CD-ROM to facilitate posting of the information on the FDA website. The CD-ROM has been revised such that it will not contain the "CONFIDENTIAL" statement in the header. The CD-ROM is enclosed in a separate envelope within the shipping container.

The document as provided may be released without redaction.

If you have any comments or questions regarding the attached, please contact me at (206) 381-6266.

Sincerely,

A handwritten signature in cursive script that reads "Mark W. Gauthier".

Mark W. Gauthier  
Senior Manager, Regulatory Affairs

cc: Nancy Kercher  
File 31100, 31543